

IN THE SPECIFICATION:

Amend the paragraphs at page 2, lines 1-6, as follows:

Figure 1 shows an exploded view of the ~~Handihaler®~~ HANDIHALER® inhaler for administering the pharmaceutical combination according to the invention in inhalettes;

Figure 2a shows a longitudinal section of the ~~Respimat®~~ RESPIMAT® nebulizer disclosed in WO 97/12687 through the atomizer with the spring under tension; and

Figure 2b shows a longitudinal section of the ~~Respimat®~~ RESPIMAT® nebulizer disclosed in WO 97/12687 through the atomizer with the spring released.

Figures 2a and 2b herein are identical to Figures 6a and 6b of WO 97/12687.

Amend the paragraph at page 9, lines 17-23, as follows:

This inhaler (~~Handihaler®~~ HANDIHALER®) for inhaling powdered pharmaceutical compositions from capsules is characterized by a housing 1 containing two windows 2, a deck 3 in which there are air inlet portions and which is provided with a screen 5 secured via a screen housing 4, an inhalation chamber 6 connected to the deck 3 on which there is a push button 9 provided with two sharpened pins 7 and movable counter to a spring 8, and a mouthpiece 12 which is connected to the housing 1, the deck 3 and a cover 11 via a spindle 10 to enable it to be flipped open or shut.

Amend the paragraphs at page 13, line 22, to page 14, line 2, as follows:

An apparatus of this kind for propellant-free delivery of a metered quantity of a liquid pharmaceutical composition for inhalation is described for example in International Patent Application WO 91/14468 and also in WO 97/12687 (cf. in particular Figures 6a and 6b),

both of which are incorporated herein by reference in their entireties. The nebulizers (devices) described therein are known by the name ~~Respimat®~~ RESPIMAT®.

This nebulizer (~~Respimat®~~ RESPIMAT®) can advantageously be used to produce the inhalable aerosols according to the invention containing the combination of active substances 1 and 2. Because of its cylindrical shape and handy size of less than 9 cm to 15 cm long and 2 cm to 4 cm wide, this device can be carried at all times by the patient. The nebulizer sprays a defined volume of pharmaceutical formulation using high pressures through small nozzles so as to produce inhalable aerosols.

Amend the paragraph at page 17, lines 15-17, as follows:

Figures 2a/b attached to this patent application, which are identical to Figures 6a/b of WO 97/12687, show the nebulizer (~~Respimat®~~ RESPIMAT®) which can advantageously be used for inhaling the aqueous aerosol preparations according to the invention.

Amend the paragraphs at page 18, line 18, to page 19, line 13, as follows:

If the formulation according to the invention is nebulized using the method described above (~~Respimat®~~ RESPIMAT®) the quantity delivered should correspond to a defined quantity with a tolerance of not more than 25%, preferably 20% of this amount in at least 97%, preferably at least 98% of all operations of the inhaler (spray actuations). Preferably, between 5 and 30 mg of formulation, most preferably between 5 and 20 mg of formulation are delivered as a defined mass on each actuation. However, the formulation according to the invention may also be nebulized by means of inhalers other than those described above, e.g., jet stream inhalers or other stationary nebulizers.

Accordingly, in a further aspect, the invention relates to pharmaceutical formulations in the form of propellant-free inhalable solutions or suspensions as described above combined with a device suitable for administering these formulations, preferably in conjunction with the ~~Respimat®~~ RESPIMAT®. Preferably, the invention relates to propellant-free inhalable solutions or suspensions characterized by the combination of active substances 1 and 2 according to the invention in conjunction with the device known by the name ~~Respimat®~~ RESPIMAT®. In addition, the present invention relates to the above-mentioned devices for inhalation, preferably the ~~Respimat®~~ RESPIMAT®, characterized in that they contain the propellant-free inhalable solutions or suspensions according to the invention as described hereinbefore.

The propellant-free inhalable solutions or suspensions according to the invention may take the form of concentrates or sterile inhalable solutions or suspensions ready for use, as well as the above-mentioned solutions and suspensions designed for use in a ~~Respimat®~~ RESPIMAT®. Formulations ready for use may be produced from the concentrates, for example, by the addition of isotonic saline solutions. Sterile formulations ready for use may be administered using energy-operated fixed or portable nebulizers which produce inhalable aerosols by means of ultrasound or compressed air by the Venturi principle or other principles.